

## REMARKS

1. The application was filed with 61 claims, of which Claims 27-61 have been withdrawn. Claims 1-26 remain pending in the application. Claims 1-4 and 11-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank"). Claims 5-10 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank") and further in view of U.S. Pat. Appl. Publ. 2003/0105424 to Sujatha Karoor et al. ("Karoor"). Claims 15, 24 and 25 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank") and further in view of U.S. Pat. 5,522,998 to Hans-Dietrich Polaschegg ("Polaschegg"). Claim 17 is rejected as unpatentable under 35 U.S.C. § 103(a) in view of Burbank and further in view of U.S. Pat. No. 4,950,259 to Denis Geary et al. ("Geary"). Claims 18-20 are rejected as unpatentable under 35 U.S.C. § 103(a) in view of Burbank and further in view of U.S. Pat. No. 4,229,299 to Steven Savitz et al. ("Savitz"). Claims 16, 21-23, and 26 are rejected as unpatentable under 35 U.S.C. § 103(a) in view of Burbank and further in view of U.S. Pat. No. 6,579,253 to Jeffrey Burbank et al. ("Burbank '253").

Finally, Claims 1 and 5-10 have been provisionally rejected on grounds of nonstatutory obviousness-type double patenting over Claims 1-11 and 59-60 of copending application 09/990,673. This application has been allowed and U.S. Pat. No. 7,241,272 issued on July 10, 2007. The undersigned attorney for the Applicants has therefore executed a terminal disclaimer which is herewith submitted to overcome the double patenting rejection.

2. Claims 1-4 and 11-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank"). Applicants traverse the rejection of Claims 1-4 and 11-14 because the Burbank reference does not teach or suggest all the limitations of Claims 1-4 and 11-14. The rejection cites Fig. 1 of Burbank as teaching all the limitations of Claim 1. At a minimum, however, Burbank does not teach a membrane device in contact with and separating the patient fluid loop from the second fluid loop.

The Office Action cites Burbank Fig. 1 as disclosing a patient fluid loop 14 including a first pump 20 and patient lumens 16, 30; a second fluid loop 80; and a membrane device 52, the membrane device 52 allegedly in contact with and separating the patient fluid loop from the

second loop 48. Membrane device 52 is not in contact with fluid loop 14 including first pump 20 and patient lumens 16, 30. Therefore, device 52 cannot separate patient loop 14 from second loop 48 or any other loop. Even if the membrane device is considered to be dialyzer 22, as cited for the rejection of Claim 2, dialyzer 22 does not separate patient loop 14 from a second fluid loop that includes a second pump and a medical fluid regenerator, as recited in Claim 1. Loop 48 merely purifies the water from the spent dialysate. Loop 48 is part of a larger system that includes regeneration loop 80 and sends fresh infusate through conduit 70 to the patient loop. Thus, the membrane device, whether Burbank's device 22 or 52, or both, does not meet the limitations of Claim 1 of separating the patient fluid loop from a second fluid loop that includes a medical fluid regenerator, because the patient fluid loop is not separated from the second fluid loop.

Accordingly, Burbank does not teach or suggest all the limitations of Claim 1, which is therefore allowable. Claims 2-4 and 11-14 depend from Claim 1 and are also allowable.

3. Claims 5-10 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank") and further in view of U.S. Pat. Appl. Publ. 2003/0105424 to Sujatha Karoor et al. ("Karoor"). Claims 5-10 depend from Claim 1 and are allowable at least because they depend from allowable Claim 1.

As to Claim 5, the Office Action admits that Burbank does not teach a nanofilter that allows urea to pass from the patient fluid loop to the second fluid loop. Office Action, p. 4, last three lines. The Office Action then states that Karoor at [0005] expresses the desire for a dialysis system that removes toxins from a patient, and that Karoor discloses a dialysis system that includes a filter allowing urea to pass from the patient fluid loop to the second fluid loop, citing Karoor paragraph [0071]. The Office Action then construes Karoor's standard dialyzer to be a nanofilter. Office Action, p. 5, lines 6-9. Karoor, however, specifically states in paragraph [0071] that in his system, "any dialyzer 20 can be used that provides a high clearance of small molecules across the dialyzer." That is to say, dialyzer 20 is a standard dialyzer and is clearly nothing novel or even special. There is no teaching in Karoor that the dialyzer is a nanofilter. Claim 5 is allowable for this additional reason. Finally, Karoor, directed to peritoneal dialysis, is non-analogous art to Burbank, which is directed to hemodialysis. The two cannot be combined because rejections under § 103(a) must be analogous art. M.P.E.P. 2141.03(a).

Claims 5-10 are allowable at least because they depend from allowable Claim 1.

4. Claims 15, 24 and 25 are rejected under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Pat. Appl. Publ. 2001/0041892 to Jeffrey Burbank et al. ("Burbank") and further in view of U.S. Pat. 5,522,998 to Hans-Dietrich Polaschegg ("Polaschegg"). Claims 15, 24, and 25 are allowable at least because they depend from allowable Claim 1. In order to combine Polaschegg with Burbank, there must be a motivation that intertwines the two. The rejection finds a motivation to combine in Polaschegg, which states in col. 2, lines 3-8, that balance chambers help to achieve a steady and constant flow of dialysis fluid. This motivation does not teach a need for improvements beyond Polaschegg's subsequent use of a single balance chamber, and teaches no need for any involvement with Burbank. In order to make a prima facie rejection, the Office Action must find motivation in Burbank, or in the problem to be solved, to seek Polaschegg, or a motivation in Polaschegg to seek and combine with Burbank.

Polaschegg seeks to provide a steady flow of dialysate using a balance chamber. The problem Burbank seeks to solve is to purify ultrafiltrate waste for reintroduction to the patient, thus reducing the patient's need for infusate. A person working on purification and reintroduction is already working on "a more efficient dialysate system," and would not be motivated to fine-tune the inflow and outflow of dialysate. A person working to fine-tune the inflow and outflow of dialysate, as in Polaschegg, would definitely not be motivated to complicate things by trying to purify and recycle ultrafiltrate. Burbank and Polaschegg both work in the same field, dialysis, but they are working on different problems. The stated motivation to combine, to provide "a more efficient dialysis system," could be used to combine Burbank with virtually anything, and thus does not provide sufficient motivation for the specific combination with Polaschegg. There is no stated motivation for the combination of the two references for the rejection of Claims 24 and 25.

Claim 15 recites a balance chamber in the second loop. Applicants traverse the rejection of Claim 15, because the stated motivation, providing a more efficient dialysis system, is insufficient to combine the references, as noted above. This also provides insufficient motivation to combine the references for the rejections of Claims 24-25.

As to Claim 24, Polaschegg does not teach or suggest an ultrafiltrate container in fluid communication with the second fluid loop. Polaschegg teaches an ultrafiltrate unit 54, which

may or may not be an ultrafiltrate container. For example, ultrafiltrate unit 54 may simply be a filter in which the ultrafiltrate is quickly filtered and the components are sent on their way.

Polaschegg also does not teach or suggest the Claim 25 limitation of "a fluid concentrate container." The present application teaches that a fluid concentrate container supplies necessary compounds, such as electrolytes and osmotic agents, to maintain the desired concentrations of those components. See paragraph [0161] of the application. The Office Action cites Polaschegg as teaching a such a container 42 in fluid communication with the second fluid loop 40. Polaschegg, however, in the specification, refers to container 42 as one for supplying fresh dialysis fluid from the dialysis fluid source 42, not supplying a concentrate. See col. 6, lines 50-51. Thus, Polaschegg does not teach a fluid concentrate container as claimed. Claims 24 and 25 are additionally allowable for these reasons.

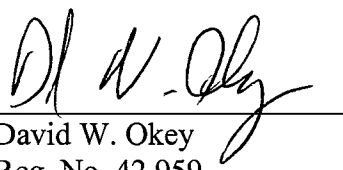
5. Claim 16-23 and 26 are allowable at least because they depend from allowable Claim 1 or from claims depending themselves from Claim 1.

6. For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same. Applicants believe that only the fee for filing the Terminal Disclaimer, submitted concurrently herewith, is due. However, if any fees are due and payable, except for the issue fee, the Commissioner is hereby authorized to charge deposit account 02-1818 for any fees which are due and owing.

Respectfully submitted,

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